OIG Publishes Study Report of Physician Owned Distributorships

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On October 23, 2013, the Department of Health and Human Services, Office of Inspector General ("OIG") published a report entitled "Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use" (the "Report").[1] The Report was provided as a response to Congressional requests to determine the extent to which physician-owned distributorships (PODs) provide spinal devices to hospitals. The Report follows prior OIG review of PODs – specifically, a 2013 Special Fraud Report[2] and a Senate Finance Report issued in 2011.[3]

In its production of the Report, the OIG reviewed 1,000 claims by 615 hospitals billed to Medicare in 2011 that included spinal fusion surgery. Each hospital associated with those claims was asked to complete a questionnaire about its knowledge of PODs. Surgeries from 7 states accounted for just over 50% of the use of PODs devices. The states with the highest reported PODs use were California, Texas, Missouri, Florida, Pennsylvania, Alabama and Georgia (collectively, 52%).

The Report noted that the exact makeup of PODs varies. Specifically, (1) whether physician-investors practice in the hospitals to which they distribute the devices, (2) whether the PODs solely distribute devices or both manufacturer and distribute their own devices, and (3) which services the PODs offer with the purchase of the devices. In several instances, the Report noted that the PODs provide physician-investors with the opportunity to profit from their own use of the devices.

PODs have been in the marketplace for more than a decade. An important cornerstone of PODs organizations is the assertion by most PODs that the arrangement can lower healthcare costs because it is a more efficient means of delivering the product to the hospital. That is, fewer "middlemen" or sales personnel equates to lower costs and ultimately savings that are passed on to the consumer. The PODs also create an opportunity to increase competition within the marketplace by allowing smaller manufacturers to compete with larger, international manufacturers. Consistent with prior OIG examinations, the Report was highly critical of these assertions.

Notable Findings

Some notable findings from the Report include:

1. In FY 2011, PODs supplied devices used in almost 20% of the spinal fusion surgeries billed to Medicare.
2. Surgeries that used POD devices used almost 2 fewer devices per surgery than surgeries that did not use POD devices.
3. Device costs for surgeries that used POD devices were not lower than those for all other surgeries.
4. The growth rate of spinal surgery after hospitals began purchasing from PODs was three times that for all hospitals.
5. The complexity of hospitals' caseloads of spinal surgeries was slightly higher for hospitals

1 Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use (Oct. 2013), http://oig.hhs.gov/oei/reports/oei-01-11-00660.asp,

2 OIG Special Fraud Alert, Physician Owned Entities (Mar. 2013) http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf,

3 Physican Owned Distributorships (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight. June 2011. http://www.finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c,

that purchased devices from PODs than that for hospitals that did not purchase from PODs.

Conclusions

Based upon its findings, the OIG reached several conclusions:

1. *The use of PODs is increasing*. With a substantial growth rate since 2009, nearly 20% of all Medicare spinal surgeries involved PODs and of the hospital's surveyed, nearly one-third reported making purchases from PODs. It is clear from the Report that notwithstanding the Special Fraud Alert and extensive concerns raised by the OIG in recent years, that PODs, if not growing, are at least deeply rooted within the spinal surgery marketplace.

2. *PODs do not appear to reduce costs or spinal surgery caseloads.* The OIG concluded that hospitals that purchase from PODs perform more spinal surgeries and have slightly more complex caseloads than hospitals that do not purchase from PODs. Though the OIG did not pursue the cause, it did determine that hospitals in its study experienced increased rates of growth in the number of spinal surgeries performed as compared to the growth rate for hospitals overall.

3. *PODs raise significant fraud and abuse concerns.* The OIG reiterated its concern that the PODs create significant concerns under the federal Anti-Kickback Statute. As supported by its findings, the OIG noted that devices sold by PODs are "physician preference items" in which the physician's choice (either of brand or design) may heavily outweigh that of the hospital's power of choice in selecting (and purchasing) the devices. Though the federal Sunshine Act will require PODs to become more transparent, the Report noted that the disclosure by hospitals and physicians to their patients is widely disparate and the ability of patients to identify potential conflicts of interest among physicians and hospitals is reduced.

Impact

The Report is an example of the OIG's consistent, multi-year, focused review of PODs. Both hospitals and physicians must carefully consider their current (or prospective) use of PODs in light of the OIG's findings and conclusions. It is clear that there is tension between the PODs (which many support as a means to reduce overall healthcare costs, while continuing to drive innovation in the marketplace) and the OIG (which does not appear to have become any more willing to accept such claims). Providers can best address the tension and the resulting uncertainty by being vigilant in their compliance efforts, specifically: (1) reviewing current conflicts of interest policies and revising the same as necessary to interface with PODs and (2) reviewing any current PODs to determine their compliance with federal and state laws.

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